

DEC 15 2000

K002971
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510(k) Summary

03 November 2000

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Manufactured by: Minitüb
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Submitted by: Richard Hampl-Portenlänger
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Classification: Accessory, Assisted Reproduction

Class: II **CFR:** 884.6120 **Procode:** 85 MQG

Predicate Device: Tokai Hit Thermo plate
K991263
8 July 1999

Heated Stages & Stage Inserts

Trade Names:

Common Names:

#12055/0004

Minitüb heating system for inverted microscope

Heating system for inverted microscope

#12055/0015

Minitüb heating system for upright microscope

Heating system for upright microscope

#12055/0031

Minitüb heating stage insert for Nikon inverted microscope

Heating stage insert for Nikon inverted microscope

#12055/0034

Minitüb heating stage insert for Olympus inverted microscope

Heating stage insert for Olympus inverted microscope

#12055/0003

Minitüb heating stage for stereo microscope, standard model

Heating stage for stereo microscope

#12055/0039

Minitüb heating stage for stereo microscope, special model for Nikon SMZ-U and Olympus SZH

Heating stage for stereo microscope, special model for Nikon SMZ-U and Olympus SZH

#12055/0009

Minitüb laboratory warming plate

Laboratory warming plate

#12055/0550

Minitüb heating stage for temperatures up to 100°C
180 x 180 mm

Heating stage 180 x 180 mm

#12055/0055

Minitüb heating stage for temperatures up to 100°C
130 x 120 mm

Heating stage 130 x 120 mm

Temperature Control Units

#12055/0050

Minitüb control unit HT50 for heated microscope stage

Control unit HT50

#12055/0200

Minitüb control unit HT200 for heated microscope stages

Control unit HT200

#12055/0300

Minitüb control unit HT300 for 2 heated microscope stages

Control unit HT300

#12055/0400

Minitüb control unit HT400 for heated microscope stages

Control unit HT400

Temperature Control Units (cont'd)

#12055/0409

Minitüb control unit HT400 for 2 heated microscope stages Control unit HT400

#12055/0205

Minitüb control unit HT50S w/high heating capacity Control unit HT50S

#12055/0350

Minitüb control unit HT300H for high temperatures Control unit HT300H

Device Descriptions:

Control Units:

A metal casing protects the electronic control unit. Digital displays and touch pads help to select the desired temperature and monitor the actual temperature. The control units HT200 and HT400 are equipped with an additional heated plate for prewarming of slides, cover glasses, counting chambers, culture dishes, etc. The control units HT300 and HT400 can control two, respectively three heated microscope stages simultaneously. All control units can be combined with all heated microscope stages. All control units and digital control modules can be easily adjusted to the required temperature. All control units have passed approval for CE mark. The temperature range is between ambient temperature and +55°C/131°F. Control accuracy is +/- 0.2°C. All control units can be switched between 200-240V/50Hz or 100-120V/60Hz.

Heating systems for original microscope stages:

Heating Systems for original stages of inverted and upright microscopes can be installed on all microscopes of leading brands. This technique combines ideal temperature control of the object on the stage with the user friendliness of the original microscope design. Modification of stages is designed specifically to match with different types and models of microscopes. The heating elements are installed on the underside of the stage and are covered with dual-component epoxy resin.

Heated insert plate (Heated stage inserts):

Heated insert plates assure in combination with the heating system of the original microscope stage an even temperature distribution on the entire surface of the inverted microscope stage. The surface is anodized aluminum which allows even temperature distribution. The heating elements are on the underside of the stage and are covered with dual-component epoxy resin. The diameter of the insert plate is available in sizes specific to the microscope OEM stages. The diameter of the central aperture can be manufactured to user specification.

Heating stages for stereo microscopes and laboratory warming plates:

The warming plate is installed on top of the transmitted or incident light base of the stereomicroscope. There is a standard size as well as customized versions with special dimensions and shape available. The light opening is covered with a glass plate for even temperature distribution. The material is anodized aluminum which allows even temperature distribution. The heating element is sandwiched between the stage and an aluminum cover plate.

Indicated Use:

Maintaining the temperature of biological material like gametes and embryos at a certain temperature is essential to cover multiple applications in reproductive medicine, biology and other areas.

Hazard Analysis:

All heating elements are hermetically sealed and allow no access for the user. Electric supply from the controller to the stage and/or the stage insert is 40V low voltage. All control units feature double fuses.

Technical Details:

<u>Ref. #</u>	<u>Dimensions</u>	<u>Weight</u>
Heated Systems, Stages & Inserts		
12055/0004		
12055/0015		
12055/0031	108 mm diam.	0.2 kg
12055/0034	110 mm diam.	0.2 kg
12055/0003	180 x 180 mm	0.85 kg
12055/0039	265 x 180 mm	1.05 kg
12055/0009	600 x 400 mm	8.0 kg
12055/0550	180 x 180 mm	0.85 kg
12055/0055	130 x 120 mm	0.45 kg
Temperature Control Units		
12055/0050	185 x 180 x 75 mm	1.8 kg
12055/0200	185 x 180 x 84 mm	2.8 kg
12055/0300	200 x 245 x 90 mm	3.3 kg
12055/0400	470 x 263 x 116 mm	7.2 kg
12055/0409	470 x 263 x 116 mm	7.5 kg
12055/0205	180 x 80 x 180 mm	1.8 kg
12055/0350	200 x 245 x 90 mm	3.3 kg

Attachments:

User's Manual

CE Certificates

Label



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Friedel MW Zander
President/CEO
Zander Medical Supplies, Inc.
755 8th Court, Suite #4
P.O. Box 650790
VERO BEACH FL 32965-0790

Re: K002971
Minitüb Heated Stage Systems
Dated: September 20, 2000
Received: September 22, 2000
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Mr. Zander:

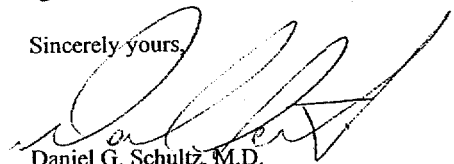
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)



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510(k) NUMBER (IF KNOWN) : K002971

DEVICE NAME : MTG - Minitüb Heated Stage Systems

INDICATIONS FOR USE :

The MTG-Minitüb Heated Stage System is indicated for maintaining the temperature of biological material like gametes and embryos at a certain temperature which is essential to cover multiple applications in reproductive medicine, biology and other areas.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of Division Sign of Device Evaluation (ODE)
Division of Re otive, Abdominal, ENT,
and Radiologic vices

510(k) Number

K002971

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter-Use
(Optional Format 1-2-96)